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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HERM SNYDER,
ADRIAN E. SMITH, and JIM NASIATKA

Appeal 2009-014502
Application 09/919,278
Technology Center 1600

Decided: March 15 2010

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M.
LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims 19-32, which are directed to a method for spray drying a feed stock to produce pharmaceutical agent particles. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the rejection of claim 32 but reverse the rejection of claims 19-31.

STATEMENT OF THE CASE

Claims 19-32 are on appeal. Claim 19 is representative of claims 19-31 and reads as follows:

Claim 19: A method for spray drying a feed stock containing a pharmaceutical agent to produce particles suitable for pulmonary administration having a narrow particle size distribution comprising:

- providing a liquid feed stock comprising a pharmaceutically active agent selected from the group consisting of [a list of specified pharmaceutical agents];
- forcing said liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes of at least one predetermined diameter, in order to produce liquid droplets;
- drying said droplets in a gas stream to produce dried particles comprising a mass median aerodynamic diameter of less than 10 microns and a particle size distribution wherein at least 70% of the mass of the particles have a diameter within a 4 micron range; and
- collecting said dried particles.

OBVIOUSNESS

Issue

The Examiner has rejected claims 19-32 under 35 U.S.C. § 103(a) as being obvious in view of Ketcham,¹ Backstrom,² and Forrester.³

The Examiner finds that Ketcham discloses “an apparatus and process for producing liquid droplets having a narrow size distribution, wherein thi[n] liquid streams are forced under pressure through a plurality of orifices in an orifice plate, wherein the thin liquid streams are vibrated to cause the

¹ Ketcham, US 4,871,489, Oct. 3, 1989

² Backstrom et al., US 5,952,008, Sept. 14, 1999

³ Forrester et al., US 4,590,206, May 20, 1986

breakup of each stream into droplets having a narrow size distribution” (Office Action mailed Jan. 4, 2006, at 2-3). The Examiner also finds that Ketcham’s apparatus has “vibrating members and a separate plate comprising holes” (*id.* at 3). The Examiner finds that Backstrom and Forrester disclose pharmaceutical compositions in the form of fine particles for inhalation (*id.* at 3-4), and concludes that it would have been obvious to one having ordinary skill in the art to use Ketcham’s apparatus to make particles containing pharmaceutical agents, as disclosed by Backstrom and Forrester (*id.* at 5-6).

Appellants contend that the Examiner erred in finding that the cited references disclose or suggest “forcing ... liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes,” as recited in claim 19 (Appeal Br. 11).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Ketcham discloses or suggests “forcing ... liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes”?

Findings of Fact

1. Ketcham discloses

[a]n apparatus and process for producing liquid droplets having a narrow size distribution. Thin liquid streams are forced under pressure through a plurality of orifices in an orifice plate. ... Also the thin liquid streams are vibrated to cause the breakup of each stream into droplets having a narrow size distribution.

(Ketcham, abstract.)

2. Figure 1 of Ketcham is reproduced below:

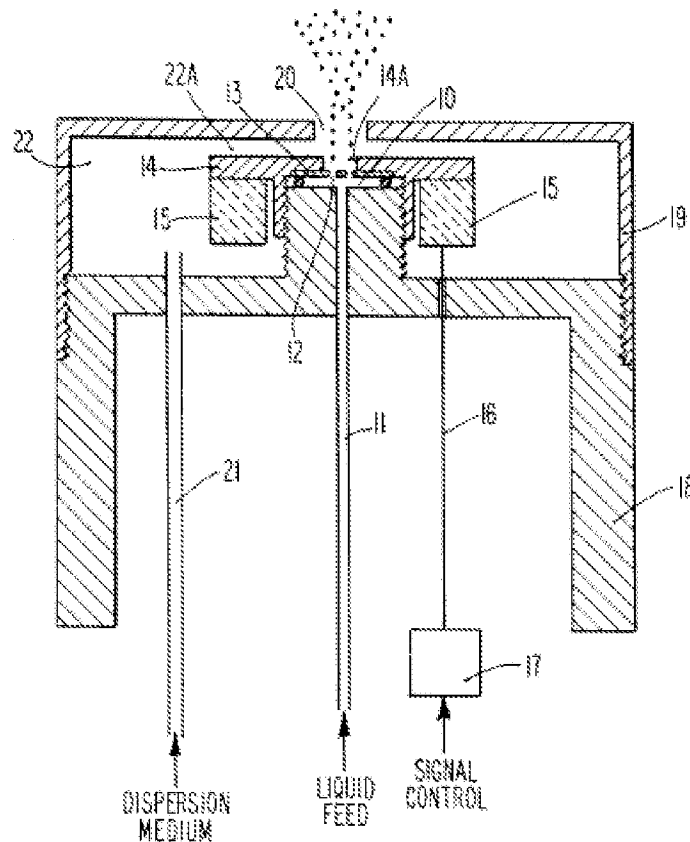


Figure 1 shows “a schematic representation of a droplet generating apparatus” (*id.* at col. 3, ll. 31-32).

3. Ketcham discloses that

FIG. 1 shows an apparatus comprising a chamber 10 for containing a body of liquid to be formed into droplets. Liquid feed tube 11 provides a source of pressurized liquid to chamber 10. ... Orifice plate 13 is integrally connected to liquid orifice cup 14, which in turn is in operative engagement with a vibratory element 15.

(*Id.* at col. 3, ll. 57-66.)

4. Ketcham discloses that the vibration of element 15 “causes a similar vibration in orifice cup 14 and hence in orifice plate 13” (*id.* at col. 4, ll. 3-4).

Principles of Law

“[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Analysis

Claim 19 is directed to a method that comprises forcing a liquid feed stock that comprises a pharmaceutical agent into “a manifold defined between a vibratable element and a plate” and forcing the feed stock through holes in the plate.

Appellants argue that Ketcham does not disclose “forcing the liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes,” as required by claim 19, “[b]ecause the chamber (10) of *Ketcham* is defined between the base (18) and the orifice plate (13), and not between the vibratory element (15) and the orifice plate (13)” (Appeal Br. 11).

The Examiner reasons that the Specification does not define the term “manifold” and that, in the absence of a definition, “the apparatus disclosed by Ketcham where the liquid feed is forced through the vibratable element and the plate comprising the holes” meets the claim limitation (Ans. 4).

We do not agree with the Examiner’s reasoning. The ordinary meaning of a manifold is “a pipe fitting with several lateral outlets for

connecting one pipe with others.”⁴ In the context of claim 19’s recitation of “forcing ... liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes ... to produce liquid droplets,” the ordinary meaning of “manifold” would indicate to one of skill in the art that the feed stock is delivered to the manifold in liquid form and then exits the manifold, as droplets, via the plate holes.

The Examiner has not indicated, by reference to figure and element number, which part of Ketcham’s device he interprets to be a “manifold.” As we understand it, the Examiner interprets the opening (14a) above plate 13 and between vibratory elements 14 in Ketcham’s device as a “manifold.” However, the Examiner has not established that element 14a meets the limitations of claim 19.

That is, claim 19 requires that a liquid feed stock is forced into a manifold defined between a vibratable element and a plate, and then forcing the stock through the plate to form droplets, whereas Ketcham discloses that a liquid feed stock is delivered to chamber 10, then forced through a plate to form droplets, which are delivered to the space above plate 13, the element defined by the Examiner to be the “manifold.” Thus, the Examiner has not adequately explained how Ketcham discloses forcing a liquid feed stock, not droplets, into a manifold between a vibratable element and a plate with holes in it. The rejection of claim 19, and dependent claims 20-31, as obvious in view of the cited references is reversed.

⁴ *Merriam-Webster Online Dictionary*, Merriam-Webster Online, accessed 7 March 2010 (<http://www.merriam-webster.com/dictionary/manifold>)

Independent claim 32 also stands rejected under 35 U.S.C. § 103(a) as being obvious in view of Ketcham, Backstrom, and Forrester. Because Appellants have not presented any arguments disputing the Examiner's rejection of claim 32 in view of the cited references, we summarily affirm the rejection.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the cited references disclose or suggest the claim limitation of "forcing said liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes."

SUMMARY

We reverse the rejection of claims 19-31 under 35 U.S.C. § 103(a). However, we affirm the rejection of claim 32 under 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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